No. 17-1229

In the Supreme Court of the United States

HELSINN HEALTHCARE S.A.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC., and
TEVA PHARMACEUTICALS INDUSTRIES, LTD.,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF OF *AMICUS CURIAE*, MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO"), IN SUPPORT OF PETITIONER

SOPHIE F. WANG
COUNSEL OF RECORD
ERIC J. MARANDETT
CHOATE HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110
(617) 248-5000
SWANG@CHOATE.COM

AUGUST 30, 2018 *COUNSEL FOR AMICUS CURIAE*

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INTEREST OF MASSACHUSETTS BIOTECHNOLOGY COUNCIL ("MASSBIO")

Founded in 1985, Massachusetts Biotechnology Council ("MassBio") is a nonprofit association of more than 1,100 biotechnology companies, academic institutions, disease foundations, and other organizations involved in life sciences and healthcare, principally based or active in the Commonwealth of Massachusetts.[1] Of the more than 600 MassBio members that are life sciences companies, more than 88% have less than 250 employees worldwide, and 74% have less than 50. These small and midsize biotechnology companies depend on both strong patent rights and collaborations with other parties to maintain their ability to research, develop, and commercialize breakthrough medicines, and to ensure that patients around the world have affordable access to those new treatments.

MassBio opposes policies and laws that threaten patient access, limit innovation, or hurt the Massachusetts life sciences industry's competitiveness in the global economy. Because of the already numerous challenges faced by small and midsize biotechnology companies and the heavy reliance of these innovators on patent protection and collaboration, MassBio is

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[1] MassBio has no financial interest in any party or the outcome of this case. This brief was neither authored nor paid for, in whole or in part, by any party. Counsel of record received timely notice of the intent to file the brief under Supreme Court Rule 37. Petitioner consented to the filing of this brief through a blanket consent letter filed with the Clerk's Office on August 1, 2018. Respondent consented via e-mail received on August 23, 2018.

particularly concerned with the uncertainty and chilling effect established by the Federal Circuit's decision below regarding the types of transactions that may trigger the "on-sale" bar. MassBio believes that its industry experience and perspective will provide useful information for the Court's consideration of the question on appeal.

SUMMARY OF ARGUMENT

This case concerns a question of critical importance to the biotechnology and pharmaceutical industries: whether public disclosure of the existence of otherwise confidential pre-marketing agreements can be used to invalidate an innovator's patent. The Federal Circuit's decision below would categorically bar patents on the basis of any public disclosure of the *mere existence* of an agreement, rather than public disclosure of the invention itself. This holding ignores both the plain language of Section 102(a)(1), as amended by the Leahy-Smith America Invents Act (AIA), and the practical realities of what is often necessary to bring life-saving medicines to market.

The decision below improperly ignores Congress' express amendment of Section 102, holding instead that despite the plain language of the amended statute, as well as the wealth of consistent legislative history, Congress did not intend to change the meaning of the on-sale bar through the AIA. The Federal Circuit thus incorrectly applied the *pre*-AIA analytical framework for determining what constitutes a commercial sale under *pre*-AIA Section 102(b) to the amended

language of AIA Section 102(a)(1), essentially rendering the amendment meaningless.

In addition, notwithstanding statements by the panel and Judge O'Malley in her later concurrence in the denial of *en banc* review, the Federal Circuit's unusually categorical analysis in the decision below extends beyond the agreement at issue and purports to apply the amended on-sale bar to any instance where the *mere existence* of an agreement concerning an invention is disclosed.

This erroneous application of the on-sale bar to activities that fall outside of the plain meaning of the amended statute disproportionately affects small and midsize biotechnology companies that depend on both valid patents and the ability to access expertise they cannot efficiently build in-house by entering into pre-marketing collaborations with other companies in order to bring new drugs to market. In particular, where other federal statutes (such as the Securities Exchange Act of 1934) may require disclosure of the existence of these types of collaboration agreements, the Federal Circuit's decision effectively renders any such agreement as an invalidating sale under Section 102. This improper result forces innovator companies to either forgo their patent rights in order to fund the development of life-saving therapies or face the prospect of never making it to market at all.

Because the Federal Circuit's interpretation of AIA Section 102(a)(1) is in direct contravention of the plain meaning and intent of the amended statute, and has a particularly devastating effect on essential collaboration efforts within the biotechn-

ology and pharmaceutical industries, it should be rejected.

ARGUMENT

I. The Federal Circuit's Decision Ignores the Plain Language of the Amended On-Sale Bar Under AIA Section 102(a)(1)

In applying the on-sale bar to both *pre*-AIA and AIA patents the same way, the Federal Circuit has treated the AIA's amendment of Section 102 as an insignificant difference in phraseology rather than intentional, substantive change. This view violates basic principles of statutory construction and should be rejected.

Before the AIA, 35 U.S.C. § 102(b) (2000), stated (emphasis added):

> A person shall be entitled to a patent unless—
>
> . . .
>
> (b) the invention was patented ***or*** described in a printed publication in this or a foreign country ***or*** in public use ***or*** on sale in this country, more than one year prior to the date of the application for patent in the United States . . .

Thus, pre-AIA Section 102 could be read to list *four* categories of activities that would bar the issuance of a patent, each of which is separated by a disjunctive "or": (1) the invention was patented, (2) the invention was described in a printed publication, (3)

the invention was in public use, and (4) the invention was on sale. Alternatively, the statute could be read to list only *two* broad categories of activities, defined by different geographic limitations, where the second "or" (underlined below) separates activities taking place both domestically and abroad ("was patented or described in a printed publication") from activities taking place only domestically ("in public use or on sale"):

> (b) the invention was patented or described in a printed publication ***in this or a foreign country or*** in public use or on sale ***in this country***, more than one year prior to the date of the application for patent in the United States . . .

In 2013, Congress amended the language of Section 102 in 35 U.S.C. § 102(a)(1) (2011) to read as follows (emphasis added):

> A person shall be entitled to a patent unless—
>
> (1) the claimed invention was patented, described in a printed publication, ***or*** in public use, on sale, ***or*** otherwise available to the public before the effective filing date of the claimed invention . . .

Notably, the AIA amendment removed the geographic limitations from this provision. It also selectively removed some of the instances of the disjunctive "or," thus changing the language of the statute to provide for a list of *three* categories of qualifying activities, the third of which includes certain identified sub-categories: (1) the invention

was patented, (2) the invention was described in a printed publication, and (3) the invention was "in public use, on sale, or otherwise available to the public."

The added catch-all modifier to the third category —that a person would not be entitled to a patent if the claimed invention "was *otherwise* available to the public" before the effective filing date of the claimed invention—makes clear that all of the previously exemplified activities within the third category are included because they make the "claimed invention" "available to the public." *See Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008), *cert. denied*, 555 U.S. 1070 (2008) ("when a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents"). This change in the text of Section 102 is consistent with the legislative history concerning the amendment. *See, e.g.*, 157 CONG. REC. S1370 (daily ed. Mar. 8, 2011) (statement of Senator Kyl) ("New section 102(a)(1) makes two important changes to the definition of non-patent prior art. First, it lifts current law's geographic limits on what uses, knowledge, or sales constitute prior art. And second, it limits all non-patent prior art to that which is available to the public. . . . Moreover, the fact that the clause 'or otherwise available to the public' is set off from its preceding clauses by a comma confirms that it applies to both 'public use' and 'on sale.' . . . Thus new section 102(a)(1) imposes a public-availability standard on the definition of all prior art enumerated by the bill—an understanding on which the remainder of the bill is predicated."); S. Rep. No. 110-259, at 9 (2008) ("Prior art also will no longer have any

geographic limitations; thus in section 102 the 'in this country' limitation as applied to 'public use' and 'on sale' is removed, and the phrase 'available to the public' is added to clarify the broad scope of relevant prior art, as well as to emphasize the fact that it must be publicly available."); *id.* at 39 ("This Manager's Amendment also added the phrase 'otherwise available to the public' to 102 to make clear that secret collaborative agreements, which are not available to the public, are not prior art."). Thus, by amending Section 102, Congress manifestly intended that in order to trigger the on-sale bar, any "sale" must first make the "claimed invention" available to the public.

It is axiomatic that "[w]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Stone v. INS*, 514 U.S. 386, 397 (1995). This Court has repeatedly and consistently rejected interpretations of statutory language that ignores express Congressional amendment. *See Husted v. A. Philip Randolph Inst.*, 138 S.Ct. 1833, 1844-45 (2018) (rejecting reading of a statute that would make a second provision "redundant" and instead adopting a reading that "gives the new language added to the Failure-to-Vote Clause 'real and substantial effect'"); *Ross v. Blake*, 136 S.Ct. 1850, 1858 (2016) (rejecting interpretation of a statute where the lower court "acted as though the amendment —from a largely permissive to a mandatory exhaustion regime—had not taken place"); *Husky Int'l Elecs., Inc. v. Ritz*, 136 S.Ct. 1581, 1586 (2016) (in view of the amended language of the Bankruptcy Reform Act of 1978 adding "actual fraud" to the list that already included "a false representation," "[i]t is therefore sensible to start with the presumption that Congress

did not intend 'actual fraud' to mean the same thing as 'a false representation'"); *United States v. Quality Shores, Inc.*, 572 U.S. 141, 148 (2014) (rejecting exception to a statute where Congress amended and repealed that exception in 1950 and had not revisited the amendment since); *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241, 258-59 (2004) (rejecting view that 28 U.S.C. § 1782 applies only when adjudicative proceedings are "pending" or "imminent" because Congress had expressly amended the statute and eliminated the "pending" language, and the amendment's corresponding legislative history was consistent with this intended result); *Pierce Cty. v. Guillen*, 537 U.S. 129, 145 (2003) (rejecting interpretation of 23 U.S.C. § 409 where such "reading would render the 1995 amendment to § 409 (changing the language from 'compiled' to 'compiled *or collected*') an exercise in futility") (emphasis in original); *Babbitt v. Sweet Home Chapter of Cmtys. for a Great Or.*, 515 U.S. 687, 701, (1995) ("Given Congress' clear expression of the ESA's broad purpose to protect endangered and threatened wildlife, the Secretary's definition of 'harm' is reasonable.").

The Federal Circuit's opinion ignores this precedent and these fundamental principles and, as a result, intentionally conflates the analysis of pre-AIA Section 102(b) with AIA Section 102(a)(1). Although the court initially stated that it was "declin[ing] the invitation by the parties to decide this case more broadly than necessary," it then held that nothing about the changes to the statute or the corresponding legislative history overruled its prior, *pre*-AIA on-sale bar cases. *See, e.g.*, *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1369-71 (Fed.

Cir. 2017). Thus, the Federal Circuit essentially acted as though the amendment "had not taken place." *Ross*, 136 S.Ct. at 1858.

The Federal Circuit's apparent explanation for its reluctance to interpret the AIA on-sale bar differently was that such an interpretation "would work a foundational change in the theory of the statutory on-sale bar." *Helsinn*, 855 F.3d at 1369. But statutory upheaval is precisely what Congress intended by enacting the AIA. *See generally* John Villasenor, *The Comprehensive Patent Reform of 2011: Navigating the Leahy-Smith America Invents Act*, Policy Brief No. 184, Brookings Institution (Sept. 2011) (the AIA "constitutes the most significant overhaul of the American patent system in decades"); 157 CONG. REC. S1362 (daily ed. Mar. 8, 2011) (statement of Senator Leahy) (the AIA provides "the first meaningful, comprehensive reforms to the nation's patent system in nearly 60 years"); 157 CONG. REC. S1495 (daily ed. Mar. 9, 2011); 157 CONG. REC. H4429 (daily ed. June 22, 2011). Where Congress has intentionally changed the language of the statute, there is no support for the Federal Circuit to rely solely on its own *pre*-AIA precedent and ignore Congress' express intent going forward.

More concerning, and despite its expressed reticence to make broad rulings, the Federal Circuit went even further than its pre-AIA precedent and misinterpreted certain floor statements by members of Congress, finding that "[i]n stating that *the invention must be available to the public* [Congress] evidently meant that *the public sale itself* would put the patented product in the hands of the public." *Helsinn*, 855 F.3d

at 1371 (emphasis added).[2] Based on these statements, the Federal Circuit then categorically held that "*after* the AIA, if *the existence of the sale is public*, the details of the invention need not be publicly disclosed in the terms of sale" in order for the sale to be invalidating. *Id.* (emphasis added).

Judge O'Malley attempted to soften this ruling in her later concurrence in support of the court's denial of *en banc* review. *See Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, App. Nos. 2016-1284,-1787 (Fed. Cir. Jan. 16, 2018) (denying *en banc*) (O'Malley, J., concurring), slip op. at 2-4. Citing back to the Federal Circuit's interpretation of the pre-AIA on-sale bar in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016) (en banc), Judge O'Malley clarified that the "single factor" of the confidentiality of the sale "is not dispositive of the analysis." *Id.* at 3. Judge O'Malley also asserted that the Federal Circuit's decision had been limited, and that all it had held "was that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public." *Id.* (emphasis in original). As support, Judge O'Malley noted that "Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI" and further pointed to the Federal Circuit's discussion of other information that had been disclosed by the 8-K SEC filing, including that

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[2] The Federal Circuit similarly conflated cases concerning the "public sale" of an invention (whereby the *invention* is placed in the public domain) with instances where the invention is *kept secret*, but the existence of an otherwise confidential or private sale regarding the invention "is made public." *Helsinn*, 855 F.3d at 1369-70 (citing *Pennock v. Dialogue*, 27 U.S. 1, 19 (1829)).

a partially-redacted copy of the agreement itself had been included with the filing, that the agreement described the claimed drug formulation in detail, and that the agreement expressly contemplated the passage of title. *Id.* (citing *Helsinn*, 855 F.3d at 1361, 1364, 1366).

Judge O'Malley's reliance on the Federal Circuit's consideration of the additional information contained in the agreement that was disclosed by the 8-K filing appears directly contrary, however, to the Federal Circuit's own conclusion that, in the post-AIA world, "if the existence of the sale is public, *the details of the invention need not be publicly disclosed in the terms of sale*" in order for the sale to trigger the on-sale bar. *Helsinn*, 855 F.3d at 1371 (emphasis added). Thus, the very information that Judge O'Malley asserted was relevant to the case and "weighed strongly in favor of finding that the on-sale bar was triggered" is precisely what the Federal Circuit held is no longer relevant or necessary after the AIA if the existence of the sale itself is made public.

For all of the reasons above, the Federal Circuit's interpretation of AIA Section 102(a)(1) cannot be squared with the plain text of the amended statute or Congress' intent. It should be rejected.

II. SECRET COLLABORATIONS ARE VITAL TO INNOVATION AND DEVELOPMENT IN THE BIOTECHNOLOGY SPACE.

Correctly applying the AIA on-sale bar is vital to industries where pre-marketing transactions and collaboration are essential for success. The erroneous holding by the Federal Circuit that the AIA on-sale bar applies by disclosure of the *existence of* the sale

of an invention, rather than disclosure of the invention *by* a sale, has a particular chilling effect on innovation and collaboration within the biotechnology industry.

Biotechnology largely remains a small company industry, and the cost of biotech development is incredibly high. On average, it takes 10 to 15 years and approximately $2.6 billion to successfully bring a new drug to market—more than double the cost during the 1990's and early 2000's. *See* Joseph A. DiMasi et al., *Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs*, 47 J. HEALTH ECON. 20-33 (2016). Because many biotechnology companies operate without revenue, these costs represent significant challenges to companies seeking market entry. *See* Lisa Eckelbecker, *Biotech Startups Face Bigger Funding Challenges Than Other Industries*, TELEGRAM & GAZETTE, June 19, 2016, http://www.telegram.com/news/20160619/biotech-startups-face-bigger-funding-challenges-than-other-industries (noting the struggles of biotech companies in securing funding and one company's solution to "develop compounds up to the point that he could license something to a pharmaceutical company for the preclinical studies that lead to human testing").

Notwithstanding the funding challenges, however, small and midsize biotechnology companies have proven to be leaders in researching and developing breakthrough therapies and cures. *See* HBM Partners, *Trends in U.S. New Drug Approvals* (Jan. 2018) at 1 ("As in previous years, the majority (76%) of NMEs approved in 2017 originated from smaller or mid-sized biopharma companies, *i.e.* companies outside of the 30 largest biopharma firms."). Because "these

smaller companies often out-license their drug candidates or were acquired themselves before approval, the number of approvals under their name"—18 in 2017—actually "understates their important contribution to pharmaceutical innovation." *Id.* at 10.

As an example, Massachusetts is a leading state for biotechnology innovation, with over 35,000 jobs classified as Biotechnology Research and Development —more than any other state except California. *See* MassBio, *2018 Industry Snapshot*, at 4, http://files.massbio.org/file/MassBio-2018-Industry-Snapshot-FINAL-8-29-18.pdf. However, of the over 600 life sciences member companies of *Amicus*, at least 88% have less than 250 employees worldwide, and 74% have less than 50. Yet, Massachusetts researchers are currently researching and developing products for patients with over 400 different medical indications, including various cancers, neurological conditions, immune disorders, Alzheimer's, and diabetes. *Id.* at 25-26. As of 2018, Massachusetts's biotechnology drug development pipeline made up nearly one-fifth of the total U.S. drug pipeline. *Id.* at 24.

Because of the high cost of drug development and the limited resources available to most small and midsize biotechnology companies (as compared to pharmaceutical giants), these companies do not have the ability or resources to build internally all of the expertise and scale required to bring a new biotechnology product all the way to market. As a result, most biotechnology companies must rely on business partners to support their research and development. In the case of Helsinn, and many similarly-situated companies, entering into distribution or supply agree-

ments with a partner is necessary to obtain sufficient upfront funding to advance pipeline products through clinical trials and to gain access to critical expertise that these small companies cannot, as a practical matter, develop themselves. *See Helsinn*, App. Nos. 2016-1284,-1787 (O'Malley, J., concurring), slip op. at 12.

The Federal Circuit has previously held that, under pre-AIA Section 102(b), "[t]here is no room in the statute and no principled reason raised by the parties or any of the amici to apply a different set of on-sale bar rules to inventors depending on whether their business model is to outsource manufacturing or to manufacture in-house." *Medicines Co.*, 827 F.3d at 1378-79. The court appeared to acknowledge then the danger of "penalizing a company for relying, by choice or by necessity, on the confidential services" of another company in assisting with the development of life-saving medicines. *Id.* But the Federal Circuit's decision below walks squarely into that danger and has created a chilling effect that disproportionately harms small and midsize biotechnology companies.

Specifically, if a potential business partner is a public company (as many companies who possess the necessary resources and funding are), the partner may be required to disclose the existence of any such transactions under federal statutes such as the Securities Exchange Act of 1934. *See, e.g.*, 15 U.S.C. §§ 78m, 78o. This is precisely what Helsinn's partner, MGI Pharma, did in this case. *See* Pet.App.22a-24a; J.A. 255-406. The Federal Circuit's decision could translate any federally mandated disclosure of the existence of an agreement (without any meaningful

disclosure of the underlying invention that is the subject of the agreement) into a relinquishment of the innovator's patent rights. Put another way, the cost of doing business with a public company to develop and commercialize products would include giving up patent rights that otherwise would be protected. The Federal Circuit's improper interpretation of AIA Section 102(a)(1) thus chills collaboration and seriously hinders the ability of small companies to obtain the resources required to bring crucial medicines to market.

CONCLUSION

For the foregoing reasons, MassBio respectfully requests that this Court reject the Federal Circuit's interpretation of AIA Section 102(a)(1) and give proper consideration to Congress' intended changes to the scope of the on-sale bar.

Respectfully submitted,

SOPHIE F. WANG
COUNSEL OF RECORD
ERIC J. MARANDETT
CHOATE HALL & STEWART LLP
TWO INTERNATIONAL PLACE
BOSTON, MA 02110
(617) 248-5000
SWANG@CHOATE.COM

COUNSEL FOR AMICUS CURIAE

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